

## **REMARKS**

This is in response to the Office Action dated April 7, 2008. With this Amendment, claims 1-4, 7, 9, and 11 are amended. Claims 6 and 8 were previously canceled. Claims 5 and 10 are canceled herein without prejudice or disclaimer. New claims 12-14 are added. All amendments and new claims are fully supported by the specification and drawings. No new matter is added. Claims 1-4, 7, 9, and 11-14 are pending in this application. In light of the foregoing amendments and following remarks, Applicant respectfully requests advancement of this application to allowance.

### **Claim Rejections – 35 U.S.C. § 112**

In the Office Action, claims 1-5, 7, and 9-11 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action notes that the product of the measured velocity time integral and the estimated cross sectional area of a heart valve is the stroke volume, and not the cardiac output. Applicant traverses the rejection based on the amendments above and the following remarks.

First, claims 5 and 10 are canceled without prejudice or disclaimer. Second, claim 1 is amended to recite, in part, a method of determining the diameter of the pulmonary valve, rather than a method of determining the cardiac output of a patient. Third, claim 9 recites a method of determining the cardiac output of a patient. The method includes, in part, (d) calculating a value for the cardiac output of the patient using the product of the velocity time integral and the cross sectional area of the heart valve. Claim 9 is now consistent with the specification.

In view of the foregoing, reconsideration and allowance of claims 1 and 9, as well as claims 2-4, 7, and 11, which ultimately depend from claim 1, are respectfully requested. Applicant notes that the amendments made to overcome the rejection of this section were not made to overcome an art based rejection, and so should not be construed in a limiting manner.

**Claim Rejections - 35 § 103**

At paragraph 5 of the subject Action, claims 1-5, 7, and 9-11 were rejected under 35 U.S.C. § 103(a) as being obvious over Phillips (U.S. Pat. No. 6,565,513) in view of Nidorf et al. (J Am Coll Cardiol 1992; 19:983-8). As noted above, claims 5 and 10 are canceled above without prejudice or disclaimer. Applicant respectfully traverses the rejection because Phillips and Nidorf, whether alone or in combination, fail to describe each element of the claims.

Phillips describes a method for the ultrasonic monitoring of cardiac output. As noted by the Examiner, cardiac output is determined by the product of the flow characteristics, the estimated cross-sectional area of the heart valve and the heart rate. The flow characteristics, in the form of the velocity time integral (VTI), is measured directly and in real time using Doppler techniques. The cross-sectional area must be calculated.

Nidorf describes equations for calculation of the diameter of the aortic valve, and hence its cross-sectional area (CSA). However, Nidorf fails to describe calculation of a diameter or a cross-sectional area of the pulmonary valve or pulmonary annular.

Nidorf addresses only the left side of the heart including the aortic valve. Nidorf experimentally established a linear relationship between the height of a person and the diameter of his or her aortic heart valve. Nidorf was able to establish these findings, in part, because current left-sided cardiac output measurements use an acceptable measurement of the diameter of the aortic valve and so, the experimental data was readily able to be correlated with the measured data. However, Nidorf does not extend to the right side of the heart, because it is difficult to directly measure the diameter of the pulmonary valve, even when using advanced echocardiography techniques, unlike the aortic valve.

Claims 1 and 9 recite, in part, determining a diameter of the pulmonary valve (claim 1) or pulmonary annular (claim 9). Both Phillips and Nidorf fail to describe determining a diameter of the pulmonary valve or pulmonary annular.

It would not have been obvious to modify the teachings of Phillips or Nidorf to determine the diameter of the pulmonary valve, as recited in claims 1 and 9. While it is known that the diameter of the pulmonary valve is slightly larger than the aortic valve, the ratio between the diameters of the two valves was unknown. Since the velocity time integral of the left and right side of the heart is also known to be different, Nidorf's work cannot automatically be applied to the right side of the heart. In mathematical terms, although the cardiac outputs of the left and right side, in a healthy heart, are known to be equal to at least a first order approximation, the equation still has four variables; left-sided VTI and CSA, and right-sided VTI and CSA. Nidorf's work provides an expression for obtaining only the left-sided CSA, and does not provide values for right-sided CSA, left-sided VTI, or right-sided VTI.

In sharp contrast, Applicant has now determined the result for right-sided CSA and the diameter of the pulmonary valve, as recited in Applicant's amended claims. Neither Phillips nor Nidorf disclose or teach Applicant's invention. Accordingly, reconsideration and allowance of claims 1 and 9 is requested. Additionally, claims 2-4, 7, and 11 that ultimately depend from claim 1, are also in condition for allowance. Applicant does not otherwise concede the correctness of the rejection and reserves the right to make additional arguments as may be necessary.

#### New Claims

Claims 12-14 are added above. Claim 12 recites, in part, calculating the diameter of the pulmonary valve. As discussed above, neither Phillips nor Nidorf disclose or suggest determining the diameter of the pulmonary valve. Claim 13 depends from claim 12. Consideration and allowance of claims 12 and 13 are respectfully requested.

Claim 14 depends from claim 9 (discussed above). Consideration and allowance of claim 14 is respectfully requested.

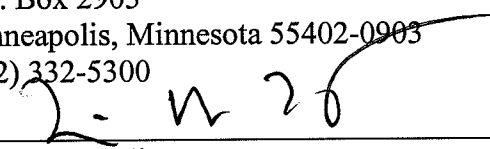
**Conclusion**

In view of this Amendment and Response, Applicant respectfully requests a Notice of Allowance. There may be additional reasons that the pending subject matter is patentably distinct from the cited references in addition to those discussed herein. Applicant reserves the right to raise any such arguments in the future. If the Examiner believes that a telephone conference would advance the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

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